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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,521	08/23/2002	Mikael Simons	100564-00111	7321

6449 7590 04/20/2007
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
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SUITE 800
WASHINGTON, DC 20005

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/089,521

Applicant(s)

SIMONS ET AL.

Examiner

Traviss C. McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed 1/3/2007 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claim 53 has been added

Remarks drawn to rejections of Office Action mailed 8/1/2006 include:

102(e) rejection: which has been maintained for reasons of record.

An action on the merits of claims 45-53 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 45-52 under 35 U.S.C. 102(e) as being anticipated by Franklin et al. (Us 6,017,557) is maintained for reasons of record.

Claim 45 is drawn to methods of modulating the sphingolipid-cholesterol microdomain in a patient in need of such modulation comprising optionally administering cholesterol sulfate to

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the patient in an amount effective to increase the detergent solubility of proteins associated with the domain. Claim 46 is drawn to a method of influencing the location of components associated with the domains using the same methods. Dependent claims limit the components to proteins, and various specific proteins. Dependent claims also limit the amount of cholesterol sulfate to 3-30 mg/kg body weight/day. Claim 52 provides the compound is cholesterol sulfate.

Franklin et al. disclose methods of treating cancer with a composition comprising cholesterol sulfate (see claim 8, for example). It is noted that while Franklin is silent to the effect of cholesterol sulfate on sphingolipid-cholesterol microdomains, Franklin must have inherently performed the methods as instantly claimed, as they administered the same compounds, in the same amounts, to the same patients, and therefor must have achieved the same results.

Franklin et al.'s methodological step of administering cholesterol sulfate would have inherently performed the method as instantly claimed. It is noted that if Franklin et al., having taken the manipulative steps described therein, had attempted to measure for the results as described in the instant application, Franklin et al. would have uncovered those results, as they are directly correlative to the method as practiced by Franklin et al. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of using cholesterol sulfate containing compositions to treat cancer, as the prior arts method would have inherently performed the method as instantly claimed. See *Ex Parte Novitski*, 26 USPQ 2d (BNA) 1389. A hypothetical example clarifies this principle. Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for "a method of making a fire by lighting a flame in the

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presence of oxygen." Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires. *EMI v. Cypress Semiconductor*, 2001 US Fed. Cir. Ct. of App. In the instant case, the prior art teaches to treat cancer with cholesterol sulfate, and applicants recognize that their methods can be used in the control of tumors (see page 9-10 of specification). The art teaches to use a dosage of from 1-1000 mg/kg body weight (see column 9, lines 55-57). The instant claims require administering cholesterol sulfate, to a patient in need thereof, in an effective amount. Franklin et al's teaching of administering cholesterol sulfate, to a patient in need thereof, in overlapping amounts, would have necessarily performed the features as instantly claimed, as it is a direct result of the compound administered.

Applicant's arguments filed 1/3/2007 have been fully considered but they are not persuasive. Applicants argue that Franklin administers cholesterol sulfate to reduce the toxicity of the active agent, and not to treat cancer itself. This is not found to be convincing as the only thing required by the instant claims is cholesterol sulfate to be administered to a patient in need thereof, which a cancer patient is. Because the cholesterol sulfate may have been administered for different reasons, does not change the fact that the art teaches every step as required by the instant claims, administering cholesterol sulfate to a patient in need thereof, the results achieved must have been inherently performed in the prior art, as the results are directly attributed to the method practiced.

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Claims 45-50 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by della Valle (US 5,229,373).

Claims 45-50 are set forth supra. Claim 53 provides the compound administered is GM₁.

Della Valle discloses methods of using gangliosides in cancer patients.

Specifically, della Valle discloses using GM₁ (see abstract, claim 1). As with Franklin et al. above, it is noted that while della Valle is silent to the effect of GM₁ on sphingolipid-cholesterol microdomains, della Valle must have inherently performed the methods as instantly claimed, as they administered the same compounds, in the same amounts, to the same patients, and therefore must have achieved the same results.

Della Valle's methodological step of administering GM₁ would have inherently performed the method as instantly claimed. It is noted that if della Valle, having taken the manipulative steps described therein, had attempted to measure for the results as described in the instant application, della Valle would have uncovered those results, as they are directly correlative to the method as practiced by della Valle. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of using GM₁ containing compositions in cancer therapy, as the prior arts method would have inherently performed the method as instantly claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

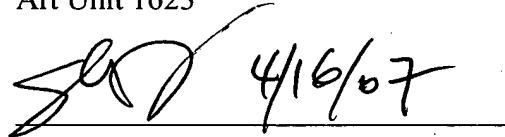
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss McIntosh
April 15, 2007

Shaojia A. Jiang
Supervisory Patent Examiner
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Handwritten signature of Shaojia A. Jiang and the date 4/16/07, written over a horizontal line.